

### **REMARKS**

This Amendment and Reply is in response to the non-final Office action mailed March 20, 2008. A Petition for an Extension of Time of Two Months and the requisite fee accompanies this filing, extending the time for response to *August 20, 2008*. Favorable reconsideration of applicants' pending claims is respectfully requested in view of the above amendments and following remarks. Following the amendments, claims 2-5, 10 and 16-27 are pending in the application, with claims 18, 19 and 20 being in independent format.

The specification has been amended, at the **CROSS-REFERENCE TO RELATED APPLICATIONS**, to delete reference to U.S. Application No. 09/724,914, filed Nov. 28, 2000, now U.S. Patent 6,565,588, and the provisional applications that the '588 patent claims priority to. An amended Application Data Sheet (ADS) is submitted herewith to reflect the same change. Applicants wish to clarify that priority to the earlier U.S. Application 09/724,914 is *not* being claimed in this application.

Minor typographical and grammatical errors in the specification as filed are also corrected. Because there were inconsistencies in the paragraph numbering incorporated in the specification as it was filed that were corrected in the published application (US 2004/0230213), the amendments presented above refer to the paragraph numbers as indicated in the published application rather than the specification as filed.

Claims 1, 6-9, and 11-15 have been cancelled and claims 18-27 have been added. Previously pending claims 2-5, 10, 16 and 17 have been amended for purposes of clarification, to provide consistent claim terminology and, in many cases, to recite multiple claim dependencies.

New claim 18 specifies an intracorporeal medical device having a rotatable torque tube and a sealing assembly for creating a liquid seal around a torque tube during operation of the device, the sealing assembly comprising a housing enclosing at least a portion of the torque tube in a manner that permits free rotation and axial translation of the torque tube and including an infusion port; and a liner surrounding the torque tube in the area of the infusion port and extending longitudinally less than the axial length of the torque tube, the liner forming a flood space within the inner surface of the liner whereby liquid enters the flood space and prevents air from entering the space external to the torque tube during operation of the device. New claim 19 recites an aspirating catheter device having a liner surrounding a rotatable torque tube and

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extending longitudinally less than the axial length of the torque tube and terminating at an intersect area to form a liquid flood space and a catheter enclosing the torque tube and the liner and extending distally beyond the intersect area, forming an aspiration lumen, whereby liquid drawn into the flood space during operation of the catheter system exits the flood space at the intersect area and enters the aspiration lumen. New claim 20 specifies a medical device having a liner surrounding a rotatable torque tube and forming a flood space extending from a sealing assembly to an intersect area, a catheter forming an aspiration lumen between the catheter and the liner and enclosing the intersect area of the liner, and a sealing assembly in communication with an infusion port providing application of liquid to the flood space during operation of the device. New claims 18-20 are presented to more clearly state the features of applicants' devices and sealing assemblies and, it is submitted, are fully supported by the specification as it was originally filed.

New dependent claims 21-26 recite additional features of applicants' claimed devices and certain components of applicants' claimed devices. It is submitted that these claims are fully supported by the specification as it was originally filed.

The devices and liquid seal assemblies described and claimed in this application are directed to sealing a rotating drive shaft without using a high tolerance bushing to provide a seal between an outer surface of the rotating drive and an opening to the outside environment. In the context of a medical device such as an aspirating catheter that also provides liquid infusion to a site of intervention, any bushing or other component that the rotating drive shaft transits must have a very high tolerance to prevent leakage of air into the space and leakage of infusion liquids from the space. During high speed rotation of the rotating drive shaft, significant friction may be generated at the interface of the bushing with the drive shaft, undesirably producing locally high temperatures. Conventional high tolerance bushings moreover don't provide an adequate seal for drive shafts that aren't solid, such as helical drive shafts that are commonly used in interventional catheter devices.

Applicants' solution to this sealing dilemma is to provide a liner surrounding the rotating drive shaft (torque tube), and to immerse a flood space in the interior of the liner with liquid. The liner and flood space extend for a portion of the length of the drive shaft less than the axial length of the drive shaft. The liquid environment surrounding the rotating drive shaft (torque

tube) provides a seal from the outside environment that is frictionless and therefore doesn't produce heat during rotation of the drive shaft. The liquid seal also prevents loss of vacuum at the proximal end of the sealing assembly. The pressure within the flood space generally decreases along the length of the liner, and the dimensions of the liner (e.g., length and cross-sectional diameter) may be adjusted as desired to reduce the flow rate in the flood space to an appropriate level while providing a liquid seal. Liquid providing the seal may eventually exit the liner at a terminal end of the liner and may be aspirated back through an aspiration lumen. That is, the liquid flowing through the flood space and providing a friction-free seal for the rotating drive shaft may be collected and withdrawn through the aspiration system.

#### **Priority**

The Examiner alleges that the disclosure of the prior-filed application, Application No. 09/826,487, fails to provide adequate support for certain claim language, namely "pressure at the liner distal end at least substantially equals the pressure of the lumen at the intersect area" and that claims 6-9 and 13 are consequently not entitled to the benefit of the parent application. Claims 6-9 and 13 are cancelled and priority to the parent application for these claims is therefore not at issue in this response. Consequently, we do not address the priority issue in this response. For the record, however, Applicants do not acquiesce in the Examiner's determination of priority and reserve their rights to establish that the specified claims and claim language are entitled to the priority of the parent application.

#### **Claim Rejections – §102(e)**

Claims 1-5, 10, 12 and 15-17 stand rejected under 35 USC §102(e) as being anticipated by Keith et al., U.S. Patent 5,938,670. These rejections are respectfully traversed in view of the newly added claims and the following remarks.

For purposes of this response, Applicants treat Keith et al. as a 35 USC §102(b) reference. Keith et al. disclose an ablation system having an exchangeable drive/catheter system and incorporating both aspiration and infusion. The disclosure includes several different arrangements for infusion of cooling liquids. The drive shaft sheath 79, which the Examiner refers to as the "liner," is a conventional sheath that overlies the outer surface of the drive shaft

and extends for substantially the length of the drive shaft to seal the drive shaft and prevent leakage of fluids from within the sheath.

The sealing assemblies of Applicants' claimed devices are not conventional infusion systems, although they may be used in conjunction with conventional infusion systems. Applicant's claimed devices incorporate a liner providing a flood space for creating a liquid seal around the rotatable torque tube during operation of the device. Claim 18 specifies that the liner surrounds the rotatable torque tube in the area of an infusion port and extends longitudinally less than the axial length of the torque tube, forming a flood space whereby sealing liquid enters the flood space and prevents air from entering the space external to the torque tube during operation of the device. Claim 19 similarly provides that the liner extends longitudinally less than the axial length of the torque tube and terminates at an intersect area. Claim 19 further specifies that a catheter encloses the torque tube and liner and extends distally beyond the intersect area, forming an aspiration lumen between the catheter and the liner, whereby liquid drawn into the flood space during operation of the catheter exits the flood space at the intersect area and enters the aspiration lumen. Claim 20 similarly specifies a medical device incorporating a catheter enclosing at least a portion of the torque tube and the liner, enclosing the intersect area of the liner and forming an aspiration lumen. Applicants do not perceive that these features are disclosed, or suggested, in the Keith et al. reference.

**Claim Rejections – §103(a)**


Claims 6-9, 11 and 13-14 stand rejected under 35 USC §103(a) as being obvious over Keith et al. in view of Shadduck, U.S. Patent Publication 2002/0095147 and Masch, U.S. Patent 4,728,319. Claims 6-9, 11 and 13-14 have been cancelled. It is submitted that none of the cited references, taken either singly or in combination, would have rendered the presently claimed subject matter obvious to one of skill in the art at the time the invention was made.

**Conclusion**

In view of the above amendments and remarks, applicants believe that the pending claims are now in condition for allowance. Early consideration and allowance of pending claims 2-5, 10 and 16-27 is respectfully requested.

The Examiner is invited to telephone the undersigned at 206.382.1191 if she has questions or if a discussion of the pending claims or the prior art references relied upon for rejection would be beneficial.

Respectfully submitted,

  
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